## **Statistical Analysis Plan (SAP)**

Official Title : Melatonin Effect in Combination with Neoadjuvant Chemotherapy to

Clinical Response in Locally Advanced Oral Squamous Cell Carcinoma

Unique ID : MLTOSCC

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## 1. Statistical Analysis

mRNA expression concentration of each sample from each gene is converted based on standard curve result. Data of study result includes HIF-1 $\alpha$  concentration, miR-210 expression, CD44 and CD133 mRNA expression before and after therapy both on intervention arm and control arm.

After the study is completed, we performed editing, coding, and inputting. Data is shown in tables and figures. Pre and post treatment data of control and intervention group is analyzed by statistical analysis tests.

Normality of data distribution is evaluated using Saphiro-Wilk test, for p value of greater than 0.05, normally distributed data is shown in Mean ± Standard Deviation (SD) while for non-normally distributed data are shown in Median (Range)

Difference between intervention and control arm (2 groups numeric) is analyzed by Saphiro-Wilk test for normality. For normally distributed data will be analyzed using independent t-test. For non-normally distributed data will be analyzed using Mann-Whitney test. Analysis is performed using IBM© SPSS® version 20. Difference is considered significant if p value is lesser than 0.05.